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| 09/623,562 | 11/16/2000 | Eva Grahn Hakansson | 48384-61007 | 4905 |

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| EXAMINER |
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SAUCIER, SANDRA E

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| ART UNIT | PAPER NUMBER |
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1651

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DATE MAILED: 12/10/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/623,562

Applicant(s)

Hakansson et al.

Examiner

Sandra Saucier

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– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirements.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☒ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 3
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

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DETAILED ACTION

Claims 1-11 are pending and are considered on the merits.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows: Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 1 is rejected under 35 U.S.C. 101 because it is directed to non-statutory subject matter.

The microbe has been obtained from nature and is presumably still available in nature. Insertion of "A biologically pure strain of" *Lactobacillus plantarum* etc.. would remove the claim from a product of nature category.

Claims 2, 10 and 11 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 112

INDEFINITE

Claims 2, 4, 5, 7-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 4 and 7 use "characterized in that". This is indefinite because it cannot be understood if the claim is open to other characteristics or if it is limited to only this characteristic. Use of "further comprising" is encouraged.

Regarding claims 5 and 8, the phrase "preferably 10^5 to 10^9 cfu" renders the claims indefinite because it is unclear whether the limitation is part of the claimed invention. See MPEP § 2173.05(d).

Regarding claims 7, 10 and 11, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are

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part of the claimed invention. See MPEP § 2173.05(d). Also, the components of the composition should be set forth in the body of the claim, not in the preamble.

Claim 9 "skimmilk" should be skimmed milk. Is the growth factor in powdered form or other form or is the composition in powdered form or other form. Please delete "in powder form or other form" because it does not appear to further limit the independent claim.

Claims 2, 10 and 11 provide for the use of *L. plantarum* DSM 11918, but, since the claims do not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

DEPOSIT

Claims 1-11 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

At least some of the claims require one of ordinary skill in the art to have access to a specific microorganism. Because the microorganism is essential to the claimed invention, it must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If the microorganism is not so obtainable or available, the requirements of 35 USC 112 may be satisfied by deposit of the microorganism. The specification does not disclose a repeatable process to obtain the microorganism and it is not clear from the specification or record that the microorganism is readily available to the public.

Since it appears that a deposit was made under the terms of the Budapest Treaty, an affidavit or declaration by applicants or a statement by an attorney of record over his/her signature and registration number, stating that the deposit has been made under the Budapest Treaty and that all restrictions imposed by the depositor on availability to the public of the deposited material will be irrevocably removed upon issuance of the patent would satisfy the deposit requirement. See 37 CFR 1.808.

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The specification must also state the date of deposit, the number granted by the depository and the name and address of the depository. See 37 CFR 1.803-1.809 for additional explanation of these requirements.

Claim Rejections – 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action: A person shall be entitled to a patent unless (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent, (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States, (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action: (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-6, 9, 10 are rejected under 35 U.S.C. 102(b) as being anticipated by or under 35 U.S.C. 103 as being obvious over US 5705160 [IDS] or US 5645830 [A].

The claims are directed to a composition comprising *Lactobacillus plantarum* DSM 11918.

The references are relied upon as explained below.

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US 5705160 discloses a biologically pure *L. plantarum* ATCC 8014 which can bind to epithelia tissue and protect subjects from growth of pathogenic bacteria in the vagina or urinary tract (Table 2). The strain is in a pharmaceutically acceptable carrier which is a yeast extract agar, a semisolid (Table 6 and col. 2, l. 49). The composition may be in the form of a paste, gel, cream, suppository or capsule comprising 10^9 microbes.

US 5645830 discloses compositions comprising *L. plantarum* ATCC 55883 (RC-20) and skim milk used for the prevention of urogenital infections. The composition may be freeze dried, or a cream, gel, liquid or suppository (col. 3, l. 25).

The Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether or not applicants' strain differs and, if so, to what extent from the strain discussed in the references. Accordingly, it has been established that the prior art *L. plantarum* ATCC 8014 or ATCC 55883, which has the same genus and species designation and shares the property of being able to inhibit enterobacteria, adheres to epithelial surfaces in the urogenital region, etc. demonstrates a reasonable probability that it is either identical or sufficiently similar that whatever differences exist are not patentably significant. Therefore, the burden of establishing novelty or unobviousness by objective evidence is shifted to applicants.

Upon clearly distinguishing the applicants' claimed strain from the cited prior art strains, the claims may be found to be directed to patentable material.

Claims 7, 8 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5705160 or US 5645830 as applied to claims 1-6, 9 and 10 above, and further in view of WO 97/02846 [N].

The claims are further directed to a composition comprising *L. plantarum* DSM 11918 and an absorbent article.

WO 97/02846 discloses the composition of *L. plantarum* and an absorbent article such as a diaper.

The substitution of *L. plantarum* ATCC 8014 or ATCC 55883 disclosed in the references of US '160 or US '830 for the generic *L. plantarum* disclosed in the

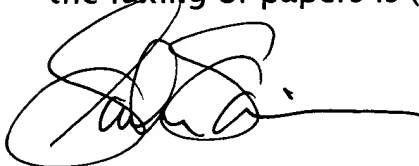
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compositions of WO 97/02846 would have been obvious because it is the substitution of equivalents in the absence of evidence to the contrary.

One of ordinary skill in the art would have been motivated at the time of invention to make this substitution in order to obtain the resulting composition as suggested by the references with a reasonable expectation of success. The claimed subject matter fails to patentably distinguish over the state of the art as represented by the cited references. Therefore, the claims are properly rejected under 35 U.S.C. § 103.

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1651. The supervisor for 1651 is M. Wityshyn, (703) 308-4743. The normal work schedule for Examiner Saucier is 8:30AM to 6:00PM Tuesday-Friday and every other Monday.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Saucier whose telephone number is (703) 308-1084. Status inquiries must be directed to the Customer Service Desk at (703) 308-0197 or (703)-308-0198. The number of the Fax Center for the faxing of papers is (703) 308-2742 or (703) 305-3592.



Sandra Saucier
Primary Examiner
Art Unit 1651
December 6, 2001